REMARKS

Applicants wish to thank the Examiner for the careful consideration given the present application as reflected in the Office action of July 3, 2008. The Amendment, of which these Remarks are a part, is being submitted after a careful consideration of the Office action and in response to the positions and conclusions enunciated in the Office action.

In summary, claims 1 through 8 are present in the case, claim 9 having been cancelled. Claims 1 through 8, which stand rejected, have been amended to more particularly define Applicants' invention and further distinguish their invention over the prior art.

In addition to modifying the claims, the present Amendment includes an amendment to the specification. The amendment to the specification does not include any new matter.

Drawings

The objection to the drawings has been rendered moot as a result of the cancellation of claim 9.

Rejection of Claims 1 Through 8 Under 35 U.S.C. 103.

Claims 1 and 8 stand rejected under 35 U.S.C. 103(a) as unpatentable over United States Patent Application Publication No. 2003/0054540 to Alford, et al. (hereinafter referred to as "Alford") in view of United States Patent No. 5,681,740 to Messier et al. (hereinafter referred to as "Messier"). In support of this rejection of claims 1 and 8, the examiner asserts that "[i]t would be an obvious design variation to mount the pump [4 of Alford] partially in the lid of [Alford] to maintain the accessibility of the switch [24]." Applicants respectfully submit that the examiner's analysis is faulty in at least two respects. First, it is clear from a reading of paragraphs [0040], [0057] and [0061] of Alford that Alford attaches importance to locating the pump assembly 4, the organ container 8, the oxygenator 21, the bubble chamber 11 and the oxygen bottle 17 together on the tray 3 so that all these components can be moved and handled as a unit. Consequently, separately attaching the pump assembly 4 to the lid 1 of Alford, as suggested by the examiner, would undermine this objective and, therefore, it would not be obvious to mount the pump 4 of Alford partially in the lid 1 of Alford as asserted by the examiner. Additionally, presumably in asserting that mounting the pump assembly 4 of Alford partially in the lid 1 of Alford would "maintain the accessibility of the switch [24]", the examiner is suggesting that the pump assembly 4 would be mounted to the top of the lid 1 of Alford since mounting the switch 24 of Alford in some manner to the underside of the lid 1 of Alford would make the switch 24 less accessible. However, to mount the pump assembly 4 to the top of the

lid 1 of Alford would destroy the function of the lid 1 which is to cover over the components in the tray 3, including the pump assembly 4.

In further support of the rejection of claims 1 and 8 over Alford and Messier, the examiner asserts that "it would have been obvious to one of ordinary skill in the art to modify the organ preservation container of Alford to include the connector [12] of Messier so that the lid [1 of Alford] is detachable." According to the examiner, the motivation for such a modification is found in Messier's teaching that "having the organ chamber with the connector portion detachable from the lid allows for the organ chamber to be removed from outside the sterile field and only the chamber delivered to the sterile field." Applicants respectfully submit that the examiner's rationale for justifying the combining of the Alford and Messier disclosures is faulty for at least three reasons. First, the lid 1 of Alford by its very nature is detachable from the remainder of the Alford apparatus so there is no reason to add an additional element in the form of a connector such as disclosed by Messier to cause the lid to become detachable. Secondly, the organ chamber 8 of Alford, because of being located in the tray 3 of Alford, can be "removed from outside the sterile field and only the chamber delivered to the sterile field" so there is no reason to provide an additional component to allow such a function to be carried out. Thirdly, the examiner has identified the component 10 of Messier as the "organ chamber" and, thus, equivalent to the organ container 8 of Alford. That being the case, it would not be obvious to detachably attach the organ container 8 of Alford to the lid 1 of Alford because, in doing so, the container 8 would not remain as an integral unit of the assembly of components that are held within the tray 3 and to separate these components would be contrary to Alford's objectives as discussed above.

It also is to be noted that the apparatus according to claim 1 of the application differs from the apparatus disclosed in Alford in that Alford lacks:

- a lid with a connector detachably connected to the lid on the side of the lid which operatively faces the organ chamber;
- a connector provided with passages, one or more connecting pieces for connection with a donor organ in the organ chamber and extending through one or more of the passages and one or more pipes connected with at least one perfusion pump; and
- at least one perfusion pump mounted at least partly in the lid.

An advantage of the claimed apparatus is that because the connector unit is located on a side of the lid which operatively faces the organ chamber (and is therefore located close to the organ when in use), the connector constitutes a simple and compact part of the apparatus which can be disposable and replaced while most of the apparatus can be re-used without constituting

a contamination hazard. Although, in an operating condition, the connector has a face forming a surface bounding the organ chamber, no problem is presented, because to provide the connector as a sterile disposable part is readily accomplished.

Another reason that it would not have been obvious to combine the Alford and Messier teachings is that Messier discloses an apparatus for storing a bioartificial organ. According to Messier, " BAOs are devices which may be designed for implantation in a recipient or which can be made to function extra-corporeally. BAOs contain living cells or tissue, which produce a biologically active molecule or provide a needed biological function to an individual. Generally, BAOs also contain a semipermeable membrane, which allows for the diffusion of nutrients to the cells and also allows the secreted cellular products and waste materials to diffuse away from the cells. " (See col. 1, lines 17-24). Further, Messier states that "once fabricated, the BAO must be maintained under suitable culture conditions to ensure the viability of the cells and the sterility of the devices until the time the BAO is to be implanted. In fact, in order to ensure that the BAOs are functional and sterile prior to implantation, the devices are held and tested for a period of many days. Sufficient testing may require holding periods of approximately 17-24 days. However, holding periods longer than even a short period of time, such as about one week, require that the fluid media surrounding the BAO be replenished periodically to provide a fresh source of nutrients and to remove waste products from the encapsulated cells. Additionally, the fluid media will require sufficient dissolved gases, including oxygen, to maintain cell viability." (See col. 2, lines 25-36).

Thus, Messier relates to devices for storing biological material under culture conditions for prolonged periods. Therefore, the skilled person looking for an efficient disposable solution for organ transport would not look to Messier. Therefore, it would not have been obvious to combine an apparatus according to Alford with features disclosed by Messier.

Moreover, combining an apparatus according to Alford with features disclosed by Messier would not produce an apparatus according to claim 1. Thus, although Messier discloses an apparatus having an organ chamber, a lid (102) and, on a side of the lid (102) facing the organ chamber, a connector (12) having openings (30, 50), Messier does not disclose:

- that the connector is mounted to the lid (102);
- that the openings (30, 50) are for receiving one or more connecting pieces for connection with a donor organ in the organ chamber and extending through one or more of the passages;

- that the connector (12) is equipped with one or more pipes connected with the pump; and
- that a pump is mounted at least partly in the lid.

It can therefore be seen that combining Messier with Alford would not have led a person skilled in the art to an apparatus according to claim 1 and, in particular, would not have led a person skilled in the art to an apparatus that can easily be separated into a compact connector unit, including the perfusion fluid conductors, that can be disposed of and a remainder that can be re-used.

Claims 2, 3, 4 and 6 have been rejected under 35 U.S.C. 103(a) as unpatentable over Alford and Messier, as applied to claims 1 and 8, and further in view of United States Patent No. 5,285,657 to Bacchi et al. (hereinafter referred to as "Bacchi"). Because claims 2, 3, 4 and 6 are dependent on claim 1, Applicants respectfully submit that claims 2, 3, 4 and 6 are patentable over Alford and Messier for the same reasons as claim 1, as discussed above. Further with respect to claim 2, it is Applicants' understanding that the examiner considers the lid 632 of Bacchi to constitute a connector having partitions. However, Applicants do not understand how it would be possible to omit the top partition, as suggested by the examiner, "to form a connector with an open side facing the lid." According to the explanation provided by the examiner, the lid and the connector are one and the same, i.e., the element 632, and it would be illogical to say that element 632 could be formed so as to have an open side facing itself. Additionally, the purpose of the partitions of Bacchi are to provide hermetically sealed compartments and modifying the Bacchi structure so as to form an open side, as suggested by the examiner, would undermine that purpose. Further, omitting the top partition as suggested by the examiner is more than merely a matter of design choice as alleged by the examiner. In Applicants' invention, providing the open side facing the lid allows for components to be located at the open side so that the components can be connected to other components supported at the top of or within the lid.

With respect to claim 3, the disposable components are required to be mounted in the connector so that the connector and the disposable components form a single-use replacement part. In Bacchi, on the other hand, none of the reservoir bag, 61, the collector bag 62, the vessel 63, the dispensing element 65, the pipework 66 or the support holder 600, which are described as disposable, is mounted in the lid/connector 632.

Concerning claim 4, that claim requires that the driving motor be "located on the side of the lid facing away from the connector and [be] detachably connected with the remaining part of the pump via an opening in the lid, which remaining part of the pump has been mounted in the

connector." In Bacchi, the driving motor is located at the sides of the box 10 and not on the lid 11, the remaining part of the pump to which the driving motor is detachably connected is not mounted in the connector 632 and that connection is not made via an opening in the lid 11. Consequently, combining the Alford, Messier and Bacchi disclosures under 35 U.S.C. 103 would not result in an apparatus as recited in claim 4.

Claims 5 and 7 have been rejected under 35 U.S.C. 103(a) as unpatentable over Alford and Messier, as applied to claims 1 and 8, and further in view of United States Patent No. 6,673,594 to Owen et al. (hereinafter referred to as "Owen"). Because claims 5 and 7 are dependent on claim 1, Applicants respectfully submit that claims 5 and 7 are patentable over Alford and Messier for the same reasons as claim 1, as discussed above. Further with respect to claim 5, as the examiner notes, the placement of the electronic module on the lid of the apparatus would allow the electronics to be connected directly to certain components of the apparatus. However, Applicants respectfully submit that simply because the result of placing the electronics on the lid of the apparatus would have such a beneficial effect does make doing so obvious under 35 U.S.C. 103, as suggested by the examiner.

With respect to claim 7, the provision of windows or the like in a manner to be able to observe and monitor the organ contained in the apparatus, as taught by Owen, does not make obvious providing a separate cover, such as cover 36 of the present invention, for a lid, such as lid 3 of the present invention, with a window in the cover so as to be able to observe a display screen in the lid.

For all the reasons set forth above, it is respectfully submitted that claims 1 through 8 are patentable over the prior art and should be allowed and a notice of allowance is respectfully requested.

If any further fees are required by this communication, please charge such fees to Deposit Account No. 16-0820, Order No. VOB-39612.

Respectfully submitted,
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